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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,700	09/25/2003	Masahiro Kajiware	6854-24-1	6367

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EXAMINER

HUANG, EVELYN MEI

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/669,700	Applicant(s) KAJIWARA, MASAHIRO	
	Examiner Evelyn Huang	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 10/220,803.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 5-16 are pending. Claims 1-4 have been canceled according to the preliminary amendment filed on 9-25-2003.

Claim Rejections - 35 USC § 112

2. The rejection for Claims 5-8 are under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons of record. The rejection is applicable to new claim 14.

The argument set forth by the Applicant has been fully considered but deemed not persuasive. The instant method of inhibiting any urease activity or inhibiting any *Helicobacter pylori* activity reaches out to as yet unidentified urease or *Helicobacter pylori* activities, the description of which are not found in the specification.

The ‘antibiotics, nitroindazole antiprotazoal agents, antiucler drugs and proton pump inhibitors’ reaches out to as yet unidentified ‘antibiotics, nitroindazole antiprotazoal agents, antiucler drugs and proton pump inhibitors’, a full description of which is not found in the specification.

Claim Rejections - 35 USC § 112

3. The rejection for Claims 5-8 under 35 U.S.C. 112, first paragraph is maintained for reasons of record. The rejection is applicable to new claim 14.

The argument set forth by the Applicant has been fully considered but deemed not persuasive. Applicant maintains that a rejection based on the lack of utility is not appropriate.

However, this is an enablement rejection, and not rejection based on the lack of utility as asserted by the Applicant. The biological pathways, such as inhibition of urease or *Helicobacter pylori* activity, would have utility only because of its link to the treatment of ulcer.

The specification only describes the inhibition of in vitro urease activity and the inhibition of in vitro *Helicobacter Pylori* activity with the inventive compound. No in vivo

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procedures have been described. Since the claims as recited embrace *any degree* of inhibition of any urease or any *Helicobacter pylori* activity, which may or may not inexorably linked to the treatment of ulcer, the scope of the claims is therefore not commensurate with that of the objective enablement, especially in view of the absence of a full written description of the as yet unidentified urease and *Helicobacter pylori* activities which the recited mechanism reaches out to as set forth in the above paragraph.

Claim 14 is directed to a method of treating mucosa injury caused by urease, further comprising other active ingredients. The method involving multiple active ingredients would involve synergism or antagonism with the inventive compound. In the absence of any working examples, undue experimentation would be required to use the invention as claimed, especially when a full description of the active ingredients (including those not yet identified) has not been found in the specification.

Since insufficient teaching and guidance have been provided in the specification, one of ordinary skill in the art therefore would not be able to use the inventive compound as claimed without undue experimentation.

Claim Rejections - 35 USC § 102

4. The rejection for Claims 5-8 under 35 U.S.C. 102(b) as being anticipated by Hirai (JP 04077476, PTO-1449) is maintained for reasons of record. The rejection is applicable to new claims 9-13, 15, 16, directed to a method of treating gastric mucosa injury caused by urease or *Helicobacter Pylori*.

The 1,2-benzisothiazol-3-(2H)-one (English abstract; also page 15, Table 1, Example 2) in the pharmaceutical composition for treating ulcer (English abstract), wherein gastric mucosa has been injured, would inherently inhibit the urease and act as an anti-*Helicobacter pylori* agent as recited in the instant claims, since it is well known in the art that *Helicobacter pylori* is the culprit of peptic ulcer disease.

Applicant maintains that Hirai does not specifically teach the inhibition of urease activity or inhibition of a *Helicobacter pylori* activity. However, the method of treating ulcer in a patient using the same prior art compound would inherently inhibit urease activity and *Helicobacter*

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pylori activity, or any mechanisms of actions. In the instant, this is especially true when *Helicobacter pylori* is commonly known to be the cause of ulcer or the recurrence of ulcer, as it is specifically described on page 28, lines 3-6 of the specification.

Applicant contends that not all ulcer is caused by *Helicobacter pylori*, and common ulcer treatments are not directed to inhibition of urease or *Helicobacter pylori* activity as shown for Prilosec (omeprazole) (PDR reference submitted with the response).

The mechanism of action, however, fails to set a demarcation from the prior art method of using the same compound for treating the same disease. Moreover, omeprazole, an H⁺/K⁺-ATPase inhibitor, has been shown also to inhibit urease and affect *Helicobacter pylori* viability in vitro (Kuhler et al. J. Med. Chem. 1995, 38(25): 4906-4916).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-12, 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claim 11, the term 'comprises' in 'gastric mucosa injury comprises chronic gastritis' is open ended and is therefore indefinite.
- b. Claim 12, the term 'comprises' in 'gastric mucosa injury comprises gastroduodenal ulcer' is open ended and is therefore indefinite.
- c. Claim 15, the term 'comprises' in 'urease comprises urease produced by *Helicobacter pylori*' is open ended and is therefore indefinite.
- d. For the method Claims 9, 16, the amount of the compound administered to the person is missing but is required.

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e. For claims 5, 7, 9, 16, it is recommended that a comma be inserted between 'or a nitrogen atom' and 'or an adduct salt thereof', and delete 'general' from 'general formula' to better define the claims.

The rejection is applicable to claims dependent on the above claims.

Conclusion

6. No claims are allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

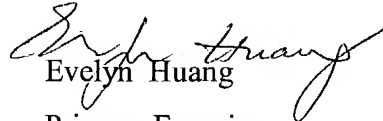
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Evelyn Huang", is positioned above the printed name.

Evelyn Huang

Primary Examiner

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